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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,804	03/22/2004	David C. Baulcombe	101044.53943D2	9959

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/805,804

Applicant(s)

BAULCOMBE ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 33-110 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 33-39, 60-65, 69-83, 100, 101, drawn to a method of silencing a target gene in an organism by PTGS, comprising introducing a silencing agent comprising short RNA molecules, classified in class 800, subclass 285, for example.
- II. Claims 40-45, 66-68, 99, 103, drawn to a method of silencing a target gene in an organism, comprising providing a DNA construct containing a promoter operably linked to a DNA which transcribes into silencing agent, classified in class 800, subclass 278, for example.
- III. Claims 46-59, drawn to a method of selecting a target region in a target gene which is desired to be silenced, classified in class 536, subclass 25.4, for example.
- IV. Claims 84-92, drawn to a method of selectively silencing a target gene in a cell, comprising introduction of exogenous nucleic acid comprising a transcribable nucleic acid construct encoding a SRM or a precursor of a SRM, classified in class 800, subclass 290, for example.

Claims 93-98, 102, 104-110 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 93-98, 102, 104-110. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or

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including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, IV are directed patentably distinct methods. The methods use different starting materials. The starting material for the method of Group I is RNA, whereas the starting material for the method of Groups II and IV is DNA. The use of different starting material requires the use of different methods of introduction into a host cell. Further, searching the inventions together would impose a serious burden. In the instant case, art searches of the methods of Group I, requiring the introduction of short RNA molecules, is not required for the prior art search of Groups II and IV. A search for the methods of introducing RNA molecules and DNA molecules would not reveal information about each other. A search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent databases. The different searches would then require subsequent in-depth analysis of the unrelated literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination any of the inventions together.

Inventions I, II, IV and III are directed to patentably distinct methods. The method of selecting a target region, involving nucleic acid extraction and purification, of Group III is not

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required for the methods of Groups I, II, and IV. Further, searching the inventions of any of the inventions together would impose a serious burden. In the instant case, an art search of the method of Group III, requiring production of nucleic acid extracts and further nucleic acid purification, is not required for the prior art search of the other groups. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent databases. The different searches would then require subsequent in-depth analysis of the unrelated literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination any of the inventions together.

Inventions II and IV are directed to patentably distinct methods. The methods have different starting materials. The method of Group IV comprises nucleic acid that encodes a precursor of a SRM, which is not required by the method of Group II. Further, searching the inventions together would impose a serious burden. In the instant case, art searches of the method of Group IV, requiring DNA that encodes precursors of SRMs, as opposed to the SRM directly, is not required for the prior art search of Group II. Search of each of these inventions would require different key word searches of each compound and of each distinctive step of each method using divergent patent and non-patent databases. The different searches would then require subsequent in-depth analysis of the unrelated literature, placing a serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination the inventions together.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for each of Groups II-IV, restriction for examination purposes as indicated is proper.

Claims 33-80, 84-110 are generic to a plurality of disclosed patentably distinct species comprising 1) plants; 2) mammals; 3) insects; 4) avian; 5) reptiles; 6) protozoans; 7) nematodes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Contact Information

Any inquiry concerning this communication from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

May 23, 2005



Ashwin D. Mehta, Ph.D.
Primary Examiner
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